

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 178

[Docket No. 99F-1422]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the expanded safe use of 2,4-di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate as an antioxidant and/or stabilizer for polypropylene, polystyrene, rubber-modified polystyrene, and styrene block copolymers intended for use in contact with food. This action responds to a petition filed by Sumitomo Chemical Co., Ltd.

DATES: This regulation is effective (insert *date of publication in the Federal Register*). Submit written objections and requests for a hearing by (insert *date 30 days after date of publication in the Federal Register*).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 26, 1999 (64 FR 28501), FDA announced that a food additive petition (FAP 9B4661) had been filed by Sumitomo Chemical Co., Ltd., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West,

Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers* for polymers (21 CFR 178.2010) to provide for the expanded safe use of 2,4-di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate as an antioxidant and/or stabilizer for polypropylene, polystyrene, rubber-modified polystyrene, and styrene block copolymers intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 178.2010 should be amended as set forth below.

In accordance with § 17 1.1 (h) (2 1 CFR 17 1. I(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 17 1.1 (h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9B4661 (64 FR 28501). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before *(insert date 30 days after date of publication in the Federal Register)*, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection

on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by revising the entry for “2,4-Di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate” to read as follows:

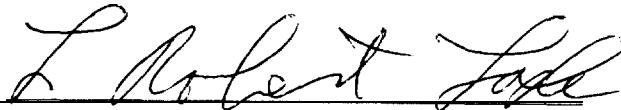
§ 178.2010 Antioxidants and/or stabilizers for polymers.

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(b) * * *

Substances	Limitations
<p>2,4-Di-<i>tert</i>-pentyl-6-[1-(3,5-di-<i>tert</i>-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate (CAS Reg. No. 123966-25-2).</p>	<p>For use only:</p> <ol style="list-style-type: none"> 1. At levels not to exceed 0.2 percent by weight of polypropylene complying with § 177.1520 of this chapter in contact with food under conditions of use D through G as described in Table 2 of § 176.170(c) of this chapter, except that polypropylene containing the additive at levels not to exceed 0.075 percent by weight may contact food under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 1.0 percent by weight of of styrene block polymers complying with § 177.1810 of this chapter. The additive is used under conditions of use D through G as described in Table 2 of § 176.170(c) of this chapter. 3. At levels not to exceed 1.0 percent by weight of polystyrene and rubber modified polystyrene complying with § 177.1640 of this chapter in contact with food under conditions of use D through G as described in Table 2 of § 176.170(c) of this chapter.

Dated: 9/21/99
September 21, 1999



L. Robert Lake
Director
Office of Policy, Planning
and Strategic Initiatives
Center for Food Safety and
Applied Nutrition

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